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Mitsuharu Hirai

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09/26/2008

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EXAMINER

BERTAGNA, ANGELA MARIE

ART UNIT

PAPER NUMBER

1637

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/536,822	<b>Applicant(s)</b> HIRAI ET AL.	
	<b>Examiner</b> ANGELA BERTAGNA	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/20/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Application***

1. Applicant's response filed on June 20, 2008 is acknowledged. Claims 1-4 and 8-10 are currently pending. In the response, Applicant amended claims 1-3, cancelled claims 5-7, and added claims 8-10.

The following rejections have been withdrawn in view of Applicant's amendment: (1) the rejection of claims 1-3 under 35 U.S.C. 112, second paragraph, and (2) the provisional rejection of claims 1-4 under 35 U.S.C. 101 for claiming the same invention as co-pending application 10/578,770.

Applicant's arguments regarding the rejections made previously under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) have been fully considered, but they were not persuasive for the reasons set forth in the "Response to Arguments" section.

The following include new grounds of rejection necessitated by Applicant's amendment and submission of an IDS on June 20, 2008. Accordingly, this Office Action is made FINAL.

### ***Information Disclosure Statement***

2. Applicant's submission of an Information Disclosure Statement on June 20, 2008 is acknowledged. A signed copy is enclosed.

### ***Specification***

3. The preliminary amendment filed on May 27, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment

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shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: (1) the recitation of "100  $\mu$ L of 1%" in paragraph 17, (2) the recitation "A positive electrode side portion of the sampling unit 26 is filled with gel in paragraph 47, (3) the recitation "the filter part 34" in paragraphs 50, 53, and 59, (4) the deletion of "The nonionic surfactant adsorbs the nucleic acid so as to prevent the cationic surfactant from adsorbing the nucleic acid." in paragraphs 66 and 67, and (5) the deletion of "whose cross-sectional area is decreased in the direction of migration" in the abstract.

Applicant is required to cancel the new matter in the reply to this Office Action.

It is noted that preliminary amendments that were not present in a national stage application as of the international filing date are not part of the original disclosure (see MPEP 1893.01(b)). In this case, Applicant has not stated where the above amendments to the specification find support in the original disclosure. It is noted that MPEP 2163.07 states, "Where a U.S. application as originally filed was in a non-English language and an English translation thereof was subsequently submitted pursuant to 37 CFR 1.52(d), if there is an error in the English translation, applicant may rely on the disclosure of the originally filed non-English language U.S. application to support correction of an error in the English translation document."

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kreader et al. (EP 0 979 868 A2; newly cited). It is noted that this document is an English language equivalent of JP 2000-146911, which was cited on the IDS filed on June 20, 2008. Therefore, this new ground of rejection was necessitated by Applicant's submission of an IDS on June 20, 2008.

These claims are drawn to a method for concentrating and purifying a nucleic acid using electrophoresis. In the method, a nucleic acid-containing sample is subjected to electrophoresis in the presence of a cationic surfactant, which adjusts the electric charge of an impurity present in the sample, thereby permitting electrophoretic separation of the nucleic acid from the impurity.

Kreader teaches a method for purifying nucleic acids using electrophoresis (see abstract).

Regarding claims 1 and 8, the method of Kreader comprises altering the electric charge of an impurity (*i.e.* a positively charged protein) present in a sample containing nucleic acids and placing the sample in an electric field to separate the nucleic acid from the impurity, thereby concentrating and purifying the nucleic acid (see paragraphs 17-19 and 27-31). In the method of Kreader, upon lowering the pH of the sample using glycine hydrochloric acid, the positively charged protein impurity migrates in the opposite direction relative to the nucleic acid when the sample is placed in an electric field (see paragraphs 18, 21, and 31). Thus, Kreader teaches all of the limitations of the instant claims 1 and 8.

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6. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorelov et al. (Physica A (1998) 249(1): 216-225; cited previously).

These claims are drawn to a method for concentrating and purifying a nucleic acid using electrophoresis. In the method, a nucleic acid-containing sample is subjected to electrophoresis in the presence of a cationic surfactant, which adjusts the electric charge of an impurity present in the sample, thereby permitting electrophoretic separation of the nucleic acid from the impurity.

Gorelov studied the interaction between DNA and a cationic surfactant (see abstract and pages 217-220). Regarding claims 1 and 2, Gorelov teaches incubating a DNA sample with a cationic surfactant and performing capillary electrophoresis, thereby purifying and concentrating the nucleic acids in the sample (see section 2.1 on page 217, section 2.4 on pages 219-220, and Figure 2). Gorelov further teaches that the cationic surfactant interacts with the DNA in the sample by displacing positively charged bound counterions (see pages 223-224). Thus, the inclusion of the cationic surfactant adjusted the electric charge of the previously bound counterions as required by the claims.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gorelov et al. (Physica A (1998) 249(1): 216-225; cited previously) in view of Irie et al. (US 6,387,235 B1; cited previously).

Claim 3 is drawn to a method for concentrating and purifying a nucleic acid using electrophoresis. In the method, a nucleic acid-containing sample is subjected to electrophoresis in the presence of a cationic surfactant and a nonionic surfactant, which adjust the electric charge of an impurity present in the sample, thereby permitting electrophoretic separation of the nucleic acid from the impurity.

Gorelov studied the interaction between DNA and a cationic surfactant (see abstract and pages 217-220). Regarding claim 3, Gorelov teaches incubating a DNA sample with a cationic surfactant and performing capillary electrophoresis, thereby purifying and concentrating the nucleic acids in the sample (see section 2.1 on page 217, section 2.4 on pages 219-220, and Figure 2). Gorelov further teaches that the cationic surfactant interacts with the DNA in the sample by displacing positively charged bound counterions (see pages 223-224). Thus, the

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inclusion of the cationic surfactant adjusted the electric charge of the previously bound counterions.

Gorelov does not teach further adding a nonionic surfactant with the cationic surfactant.

Irie teaches a method and apparatus for separating DNA molecules by capillary electrophoresis (see abstract and column 4, line 59 – column 6, line 59). Regarding claim 3, Irie teaches that the electrophoresis buffer includes the nonionic surfactant Tween 20 to prevent adsorption of the DNA molecules in the detection chamber (column 9, lines 26-34).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to further include a nonionic surfactant when performing the method taught by Gorelov. An ordinary artisan would have been motivated to do so, since Irie taught that inclusion of a nonionic surfactant minimized undesirable DNA adsorption during the detection step (see column 9, lines 26-34). Since both Gorelov and Irie used capillary electrophoresis to separate and purify nucleic acids, an ordinary artisan would have had a reasonable expectation of success in including a nonionic surfactant in the method of Gorelov as suggested by Irie. Thus, the method of claim 3 is *prima facie* obvious over Gorelov in view of Irie in the absence of secondary considerations.

9. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon, III et al. (US 6,129,828; cited previously) in view of Asai (US 6,165,758; cited previously).

These claims are drawn to a method for concentrating and purifying a nucleic acid using electrophoresis and at least one surfactant. In the method of claims 1 and 2, a nucleic acid-containing sample is subjected to electrophoresis in the presence of a cationic surfactant, which



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adjusts the electric charge of an impurity present in the sample, thereby permitting electrophoretic separation of the nucleic acid from the impurity. In the method of claims 3 and 4, the cationic surfactant adsorbs to an impurity in the sample, thereby permitting purification of the nucleic acid from the impurity. The method of claims 3 and 4 further includes a nonionic surfactant whose concentration is adjusted to control to adsorption of the cationic surfactant to the impurity.

Sheldon teaches a method for concentrating and purifying nucleic acids using electrophoresis (see abstract and column 5, line 60 – column 6, line 59). The method of Sheldon separates nucleic acids from impurities using affinity or mobility-based methods (see column 6, lines 2-7 and lines 28-59; see also column 9, line 59 – column 10, line 13). Sheldon teaches that the charge or electrophoretic mobility of contaminants (*e.g.* proteins present in a crude cell lysate) can be altered to permit their separation from the desired nucleic acids (see column 9, line 59 – column 10, line 13).

Sheldon further teaches that protein traps comprising PVDF, nitrocellulose, hydrophobic materials, negatively charged materials, or positively charged materials can be used to remove protein impurities from the nucleic acid-containing sample (column 12, lines 47-55). Sheldon teaches that these traps can further include detergents or surfactants (column 12, lines 53-58), but does not expressly teach using the surfactant to modify the charge of an impurity in the sample.

Asai teaches a method for separating an enzyme (CC acylase) from a contaminant protein (deacetylase) that comprises adding a cationic surfactant to the sample to selectively aggregate and precipitate the deacetylase contaminant (see abstract and column 2, lines 20-42; see also Example 1 and Table 1 at columns 5-6). Asai teaches that the deacetylase contaminant could not

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be removed by conventional means since its chromatographic behavior is essentially identical to that of CC acylase (column 1, lines 42-64). Asai also teaches that non-ionic surfactant could be used to achieve the same purpose (see Example 1 and Table 1 at columns 5-6).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to apply the teachings of Asai to the method taught by Sheldon. Since Asai taught that cationic or nonionic surfactants could be used to aggregate and remove a protein contaminant (see column 2, lines 20-42 and Example 1 at columns 5-6), an ordinary artisan would have been motivated to use a cationic or nonionic surfactant in the method of Sheldon to trap, and thereby, alter the electric charge of protein contaminants, thus permitting electrophoretic separation of the desired DNA molecules. An ordinary artisan would have been further motivated to use a mixture of cationic and nonionic surfactant in the method taught by Sheldon, since Asai taught that both types of surfactant were useful for aggregating and precipitating contaminating proteins (see Table 1 in column 6). As noted in MPEP 2144.06, "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)." Finally, regarding claim 4, attention is directed to MPEP 2144.05, which states, "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. '[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.' In re Aller, 220 F.2d 454, 456, 105

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USPQ 233, 235 (CCPA 1955).” In this case, an ordinary artisan would have recognized that the surfactant concentrations were results-effective variables that should be optimized in order to maximize removal of protein contaminants without hindering nucleic acid separation. Thus, optimization of the cationic and nonionic surfactant concentration is *prima facie* obvious in the absence of secondary considerations.

10. Claims 2-4, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kreader et al. (EP 0 979 868 A2; newly cited) in view of Helenius et al. (Proceedings of the National Academy of Sciences, USA (1976) 74(2): 529-532; newly cited).

As noted above, the Kreader reference is an English language equivalent of JP 2000-146911, which was cited on the IDS filed on June 20, 2008. Therefore, this new ground of rejection was prompted by Applicant's submission of an IDS on June 20, 2008. Also, the addition of new claims 9 and 10 necessitated the citation of the Helenius reference.

Claims 2 and 9 are drawn to a method for purifying and concentrating nucleic acids using electrophoresis. In the method, a cationic surfactant is added to a sample containing nucleic acids so as to alter the charge of an impurity in the sample, and then the sample is subjected to an electric field to concentrate and purify the nucleic acid. Claims 3, 4, and 10 are drawn to a method for purifying and concentrating nucleic acids using electrophoresis. In the method, a cationic surfactant and a non-ionic surfactant are added to a sample containing nucleic acids so as to alter the charge of an impurity in the sample, and then the sample is subjected to an electric field to concentrate and purify the nucleic acid.

Kreader teaches a method for purifying nucleic acids using electrophoresis (see abstract).

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Regarding claims 2-4, 9 and 10, the method of Kreader comprises altering the electric charge of an impurity (*i.e.* a positively charged protein) present in a sample containing nucleic acids and placing the sample in an electric field to separate the nucleic acid from the impurity, thereby concentrating and purifying the nucleic acid (see paragraphs 17-19 and 27-31). In the method of Kreader, upon lowering the pH of the sample using glycine hydrochloric acid, the positively charged protein impurity migrates in the opposite direction relative to the nucleic acid when the sample is placed in an electric field (see paragraphs 18, 21, and 31).

Kreader does not teach that the method comprises adding a cationic surfactant and a nonionic surfactant to the sample.

Helenius analyzed the electrophoretic mobility of seventeen hydrophilic proteins and five amphiphilic proteins in the presence of: (1) the nonionic surfactant Triton X-100, (2) a mixture of a nonionic surfactant (Triton X-100) and an anionic surfactant (sodium deoxycholate), and (3) a mixture of a nonionic surfactant (Triton X-100) and a cationic surfactant (CTAB) (see abstract and page 529). Regarding claims 2-4, 9, and 10, Helenius teaches that the amphiphilic proteins migrated toward the anode in the presence of the Triton X-100/sodium deoxycholate mixture and toward the cathode in the presence of the Triton X-100/CTAB mixture (see abstract, pages 530-531, and Figures 2-4). Helenius teaches that the amphiphilic proteins interact with the mixtures of charged and nonionic surfactant molecules to form protein-surfactant complexes comprising neutral and charged surfactant molecules (page 529, column 1). Helenius states that "The net charges of the complexes are thus dependent on the charge of the detergents used, resulting in a clear-cut difference in electrophoretic mobility of the amphiphilic proteins when electrophoresed in cationic and anionic detergent mixtures (page 529, column 1)."

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Helenius also states that "The detergent-induced shift in mobility provides a simple, rapid, and sensitive method for distinguishing between hydrophilic and amphiphilic proteins (abstract)."

Further regarding claims 3 and 4, Helenius expressly teaches that using a mixture of a nonionic and cationic surfactant is desirable to keep the structures of the protein-surfactant complexes as constant as possible (see page 531, column 1).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to apply the teachings of Helenius to the method of Kreader. An ordinary artisan would have been motivated to use a mixture of a nonionic and cationic surfactant in order to shift the migration of contaminating amphiphilic proteins present in the sample of Kreader to the cathode (*i.e.* in the opposite direction from the nucleic acids) when practicing the electrophoretic purification method of Kreader, since Helenius taught that detergent-induced mobility shifts provided a rapid, simple, and sensitive method for discriminating between differently charged species present in a sample (see abstract and page 531, column 2). An ordinary artisan would have recognized from the teachings of Helenius that adding a mixture of a nonionic and cationic surfactant to the mixture of Kreader would have achieved the same function as the pH reduction taught by Kreader, namely, electrophoretic migration of an impurity present in the sample in a direction opposite to that of the nucleic acids, and therefore, would have been motivated to alter the electrophoretic migration of an impurity present in the sample of Kreader by using a mixture of non-ionic and cationic surfactant to alter its electric charge. Since Helenius taught that the net charge of the surfactant mixture determined the electric charge of the protein-surfactant complexes (see page 529, column 1), an ordinary artisan would have had a reasonable

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expectation of success in applying the teachings of Helenius to the method of Kreader. Finally, regarding claim 4, an ordinary artisan would have recognized that the concentrations of the nonionic and cationic surfactants concentrations were results-effective variables that should be optimized in order to maximize the removal of protein contaminants without hindering nucleic acid separation. An ordinary artisan would have optimized these results-effective variables using routine experimentation and would have had a reasonable expectation of success in doing so. As noted in MPEP 2144.05, performing routine experimentation to optimize results-effective variables, such as concentration is *prima facie* obvious in the absence of unexpected results. Thus, the methods of claims 2-4, 9, and 10 are *prima facie* obvious over Kreader in view of Helenius in the absence of secondary considerations.

### ***Response to Arguments***

11. Applicant's arguments filed on June 20, 2008 have been fully considered, but they were not persuasive.

Regarding the rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Gorelov and the rejection of claim 3 under 35 U.S.C. 103(a) as being unpatentable over Gorelov in view of Irie, Applicant first argues that the claimed invention is directed to a method for purifying nucleic acids based on the binding of surfactants to impurities present in a sample containing nucleic acids, whereas Gorelov teaches binding surfactants to DNA (see page 5). This argument was not persuasive, because the claims do not require the surfactant to bind an impurity in the sample to adjust the electric charge of the impurity. Claim 1 recites "adjusting the electric charge of an impurity in the sample" by any means and does not require the presence

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of a surfactant. Claim 2 recites adding a cationic surfactant to a sample so as to adjust the electric charge of an impurity in the sample, and therefore, does not require that the electric charge of the impurity is adjusted by binding of the surfactant to the impurity. It is noted that, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant also argues that the teachings of Gorelov are concerned with analyzing the nature of the binding of surfactant to DNA rather than purifying DNA (see page 5). This argument was not persuasive, because in performing high performance capillary electrophoresis of a DNA sample in the presence of a surfactant, Gorelov inherently purified and concentrated the DNA present in the sample.

Finally, Applicant argues that the sodium counterions present in the sample of Gorelov are not an impurity, and that the method of Gorelov does not result in purification of DNA from the sodium counterions displaced by the surfactant (see page 5). This argument was not persuasive, because Gorelov expressly states, "[S]urfactant cations exchange with condensed sodium counterions on the surface of DNA (page 223, last paragraph)." Thus, in the method of Gorelov, cationic surfactant molecules displace sodium counterions present on the surface of the DNA, resulting in a higher concentration of free sodium ions in the solution. These free sodium ions will inherently migrate differently in the capillary electrophoresis method taught by Gorelov, thus resulting in purification of the DNA from this impurity. Finally, it is noted that Applicant has not expressly defined an impurity. Since positively charged counterions, such as sodium ions, are often removed from DNA samples (see pages 4-7 of Smarason et al. (US

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2003/0186247 A1; newly cited)), the sodium counterions that are separated from DNA in the method of Gorelov are an impurity. Since Applicant's arguments were not persuasive, the rejections have been maintained.

Regarding the rejection of claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over Sheldon in view of Asai, Applicant argues that the combined teachings of the references do not result in all of the claimed limitations, in particular, the requirement for the adjustment of the electric charge on the impurity to occur before placing the sample in an electric field (see page 6). This argument was not persuasive, because the combined teachings of Sheldon and Asai result in this step. When applying the teachings of Asai to the method of Sheldon, an ordinary artisan would have recognized that the cationic and/or non-ionic surfactant should be added to the sample prior to conducting the electrophoretic separation taught by Sheldon. Thus, the combined teachings of Sheldon and Asai result in all of the claimed limitations, and therefore, the rejection has been maintained.

### ***Conclusion***

12. No claims are currently allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bellon et al. (US 5,928,484) teaches using a combination of cationic complexes and non-ionic surfactants to separate a target protein from other proteins present in a sample (see abstract and column 3, line 59 - column 4, line 67).



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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Also, Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on June 20, 2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 9- 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/  
Primary Examiner, Art Unit 1637

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